**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 18, 2014

Johnson & Johnson Vision Care, Inc.
Mr. Scott Durland
Senior Manager, Regulatory Affairs
7500 Centurion Parkway, Suite 100
Jacksonville, Florida 32256

Re: K141670
Trade/Device Name: ACUVUE® (etafilcon A) Soft Contact Lens for Presbyopia, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker for Daily Wear
Regulation Number: 21 CFR 886.5925 (b) (1)
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: June 20, 2014
Received: June 23, 2014

Dear Mr. Durland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K141670

Device Name
ACUVUE® (etafilcon A) Soft (hydrophilic) Contact Lens for Presbyopia, Clear & Tinted (Visibility and/or Cosmetically) with UV Blocker for Daily Wear

Indications for Use *(Describe)*
ACUVUE® (etafilcon A) Soft (hydrophilic) Contact Lens for Presbyopia (Multifocal), Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker is indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes who may need up to 4.00D of ADD power and have 0.75D of astigmatism or less.

ACUVUE® (etafilcon A) Soft (hydrophilic) Contact Lens for Presbyopia (Multifocal-Toric), Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker is indicated for daily wear for the optical correction of refractive ametropia (myopia, hyperopia, and/or astigmatism) and presbyopia in phakic or aphakic persons with non-diseased eyes who may need up to 4.00D of ADD power and have 10.00D of astigmatism or less.

ACUVUE® (etafilcon A) Soft (hydrophilic) Contact Lens for Presbyopia, with UV Blocker, when Cosmetically Tinted, is also indicated for daily wear to enhance or alter the appearance of the eye.

ACUVUE® (etafilcon A) Soft (hydrophilic) Contact Lens for Presbyopia, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker for Daily Wear contains a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.

Eye Care Practitioners may prescribe the ACUVUE® (etafilcon A) Soft (hydrophilic) Contact Lens for Presbyopia either for single-use disposable wear or frequent/planned replacement wear with cleaning, disinfection, and scheduled replacement.

When prescribed for single-use disposable wear, the ACUVUE® (etafilcon A) Soft (hydrophilic) Contact Lens for Presbyopia is to be discarded after each removal.

When prescribed for frequent/planned replacement wear, the ACUVUE® (etafilcon A) Soft (hydrophilic) Contact Lens for Presbyopia is to be cleaned, rinsed, and disinfected each time the lens is removed. The contact lens is to be discarded after the recommended wearing period as prescribed by the Eye Care Professional. When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection system only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510(K) SUMMARY

## Submitter Information


| | |
|---|---|
| Company: | Johnson & Johnson Vision Care, Inc.<br>7500 Centurion Parkway, Suite 100<br>Jacksonville, FL 32256 |
| Contact Person: | Scott Durland |
| Email: | sdurland@its.jnj.com |
| Telephone: | 904-443-3548 |
| FAX: | 904-443-1424 |
| Date: | June 20, 2014 |


## Identification of the Device

| | |
|---|---|
| Common Name: | Soft Contact Lens |
| Device Name: | ACUVUE® (etafilcon A) Soft (hydrophilic) Contact Lens for Presbyopia, Clear and Tinted (Visibility and/or Cosmetically) with UV (ultraviolet) Blocker for Daily Wear |
| Classification Name: | Soft (Hydrophilic) Contact Lens, Daily Wear |
| Device Classification: | Class II, 21 CFR 886.5925 (b) (1) |
| Product Code: | LPL, MVN |

## Predicate Device(s)

- Material: VISTAKON® (etafilcon A) Soft (hydrophilic) Contact Lens, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker for Daily Wear most recently cleared via K062614, hereafter also referred to VISTAKON® (etafilcon A);
- Optical Design: CIBA VISION[i] (lotrafilcon B) soft contact lenses cleared via K073459, hereafter also referred to CIBA VISION (lotrafilcon B)

[i] 3rd party trademarks mentioned herein are trademarks of Novartis AG Corporation.

## Description of Device

The ACUVUE® (etafilcon A) Soft (hydrophilic) Contact Lens for Presbyopia, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker for Daily Wear is a soft (hydrophilic) contact lens available in a multifocal and/or multifocal-toric design. The lens material (etafilcon A) is a copolymer of 2-hydroxyethyl methacrylate and methacrylic acid cross-linked with 1,1,1-trimethylol propane trimethacrylate and ethylene glycol dimethacrylate. The composition of the lens is 42% etafilcon A and 58% water by weight when hydrated and stored in buffered saline solution with or without povidone. The lens is supplied in a sterile state.

The ACUVUE® (etafilcon A) Soft (hydrophilic) Contact Lens for Presbyopia, Visibility Tinted with UV Blocker for Daily Wear, is tinted blue using Reactive Blue Dye #4 to make the lens more visible for handling. A benzotriazole UV absorbing monomer is used to block UV radiation. The UV Blocking for ACUVUE® (etafilcon A) Soft (hydrophilic) Contact Lenses for Presbyopia, Visibility Tinted with UV Blocker averages 97% in the UVB range of 280 nm to 315 nm and 82% in the UVA range of 316 nm to 380 nm.

The ACUVUE® (etafilcon A) Soft (hydrophilic) Contact Lens for Presbyopia, Cosmetically Tinted with UV Blocker for Daily Wear, contains a pigmented area that will enhance or alter the appearance of the eye. The lens is colored with one or more of the following color additives: iron oxides, titanium dioxide, phthalocyaninato (2-) copper, phthalocyanine green, vat orange 1, and Reactive Blue Dye #4.

S5 Table 1, S5 Table 2, and S5 Table 3 contain property and parameter ranges for the subject device.

**S5 Table 1: Material properties**

| | |
|---|---|
| Water Content | 58% |
| Refractive Index (@ 20°C) | 1.40 |
| Oxygen Permeability (Fatt method, edge corrected) | $21.4 \times 10^{-11}$ ($cm^2$/sec)(mL $O_2$/mL * mm Hg) |
| Light Transmission - Visible | Minimum 85% |
| Light Transmission - UVA (316 nm to 380 nm) | <30.0% |
| Light Transmission - UVB (280 nm to 315 nm) | <5.0% |

**Note:** UVA = ultraviolet A, UVB = ultraviolet B

**S5 Table 2: Parameter ranges**

| | |
|---|---|
| Diameter | 12.0 mm to 15.0 mm |
| Center Thickness | 0.060 mm to 1.000 mm |
| Base curve | 7.85 mm to 10.00 mm |
| Powers | -20.00D to +20.00D |
| Multifocal ADD powers | up to +4.00D |

**S5 Table 3: Additional parameter ranges for the multifocal-toric design**

| | |
|---|---|
| Axis | 2.5° to 180° |
| Cylinder | Up to -10.00D |

## Intended Use

The intended use of ACUVUE® (etafilcon A) Soft (hydrophilic) Contact Lens for Presbyopia, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker for Daily Wear is the same as the device previously cleared under K062614. The specific indications are listed below.

ACUVUE® (etafilcon A) Soft (hydrophilic) Contact Lens for Presbyopia (Multifocal), Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker is indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes who may need up to 4.00D of ADD power and have 0.75D of astigmatism or less.

ACUVUE® (etafilcon A) Soft (hydrophilic) Contact Lens for Presbyopia (Multifocal-Toric), Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker is indicated for daily wear for the optical correction of refractive ametropia (myopia, hyperopia, and/or astigmatism) and presbyopia in phakic or aphakic persons with non-diseased eyes who may need up to 4.00D of ADD power and have 10.00D of astigmatism or less.

ACUVUE® (etafilcon A) Soft (hydrophilic) Contact Lens for Presbyopia, with UV Blocker, when Cosmetically Tinted, is also indicated for daily wear to enhance or alter the appearance of the eye.

ACUVUE® (etafilcon A) Soft (hydrophilic) Contact Lens for Presbyopia, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker for Daily Wear contains a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.

Eye Care Practitioners may prescribe the ACUVUE® (etafilcon A) Soft (hydrophilic) Contact Lens for Presbyopia either for single-use disposable wear or frequent/planned replacement wear with cleaning, disinfection, and scheduled replacement.

When prescribed for single-use disposable wear, the ACUVUE® (etafilcon A) Soft (hydrophilic) Contact Lens for Presbyopia is to be discarded after each removal.

When prescribed for frequent/planned replacement wear, the ACUVUE® (etafilcon A) Soft (hydrophilic) Contact Lens for Presbyopia is to be cleaned, rinsed, and disinfected each time the lens is removed. The contact lens is to be discarded after the recommended wearing period as prescribed by the Eye Care Professional. When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection system only.

## Technological Characteristics

The technological characteristics of the ACUVUE® (etafilcon A) Soft (hydrophilic) Contact Lens for Presbyopia are compared to the characteristics of the predicate devices, VISTAKON® (etafilcon A) and CIBA VISION (lotrafilcon B) in S5 Table 4, S5 Table 5, and S5 Table 6.

**S5 Table 4: Material and Physicochemical Comparison to VISTAKON® (etafilcon A)**

| Property | Predicate Device (K062614) | Subject Device |
|---|---|---|
| Material | etafilcon A | Same as predicate |
| FDA Category (Group) | Group IV (high water, ionic polymer) | Same as predicate |
| UV Blocker | Yes | Same as predicate |
| Water Content, % | 58 | Same as predicate |
| Refractive Index @ 20°C | 1.40 | Same as predicate |
| Dk[a], edge corrected | 21.4 | Same as predicate |
| Specific Gravity (calculated) | 0.98 – 1.13 | Same as predicate |

[a] Dk units = x $10^{-11}$ ($cm^2$/sec)(mL $O_2$/mL * mm Hg)

**Note:** UV = ultraviolet

**S5 Table 5: Multifocal Design Comparison to CIBA VISION[ii] (lotrafilcon B) (Air Optix[iii] Aqua Multifocal)**

| Property | Predicate Device (K073459) | Subject Device |
|---|---|---|
| Optical Design | Progressive Asphere[a] | Same as predicate |

[a] based on available public information and JJVCI measurements

[ii] 3rd party trademarks mentioned herein are trademarks of Novartis AG Corporation.

[iii] 3rd party trademarks mentioned herein are trademarks of Novartis AG Corporation.

## S5 Table 6: Indication Comparison

| | Predicate Device | Predicate Device | Subject Device |
|---|---|---|---|
| | **CIBA VISION[a] (lotrafilcon B) (K073459)** | **VISTAKON® (etafilcon A) (K062614)** | **ACUVUE® (etafilcon A) Soft (hydrophilic) Contact Lenses for Presbyopia** |
| Multifocal | for the optical correction of refractive ametropia (myopia & hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes who may require reading addition of +3.00D or less and who may have up to approximately 1.50D of astigmatism | for the optical correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes who may have 0.75D of astigmatism or less | for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes who may need up to 4.00D of ADD power and have 0.75D of astigmatism or less |
| Multifocal-Toric | for the optical correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in phakic or aphakic persons with non-diseased eyes. The lenses may be worn by persons who have +6.00D or less of refractive and/or corneal astigmatism | for the optical correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes who may have 10.00D of astigmatism or less | for the optical correction of refractive ametropia (myopia, hyperopia, and/or astigmatism) and presbyopia in phakic or aphakic persons with non-diseased eyes who may need up to 4.00D of ADD power and have 10.00D of astigmatism or less |
| Cosmetically tinted | N/A | to enhance or alter the apparent color of the eye | to enhance or alter the appearance of the eye |
| UV statement | N/A | helps protect against transmission of harmful UV radiation to the cornea and into the eye | contains a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye |

**S5 Table 6: Indication Comparison (Continued)**

| | Predicate Device | Predicate Device | Subject Device |
|---|---|---|---|
| | **CIBA VISION[a] (lotrafilcon B) (K073459)** | **VISTAKON® (etafilcon A) (K062614)** | **ACUVUE® (etafilcon A) Soft (hydrophilic) Contact Lenses for Presbyopia** |
| Wear Schedule | The lenses may be prescribed for daily wear with removal for cleaning and disinfection (chemical, not heat) prior to reinsertion, as recommended by the eye care professional. | May be prescribed for daily wear. Eye Care Practitioners my prescribe the lenses either for single-use disposable wear or frequent/planned replacement wear with cleaning, disinfection, and scheduled replacement (see "Wearing Schedule").<br>When prescribed for frequent/planned replacement wear, the VISTAKON® (etafilcon A) contact lens is to be cleaned, rinsed, and disinfected each time the lens is removed.<br>The etafilcon A contact lens is to be discarded after the recommended wearing period as prescribed by the Eye Care Professional. When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection system only.<br>When prescribed for single-use disposable wear, (See "Wearing Schedule") the VISTAKON® (etafilcon A) contact lens is to be discarded after each removal. | Eye Care Practitioners may prescribe the lenses either for single-use disposable wear or frequent/planned replacement wear with cleaning, disinfection, and scheduled replacement.<br>When prescribed for single-use disposable wear, the ACUVUE® (etafilcon A) Soft Contact Lens for Presbyopia is to be discarded after each removal.<br>When prescribed for frequent/planned replacement wear, the ACUVUE® (etafilcon A) Soft Contact Lens for Presbyopia is to be cleaned, rinsed, and disinfected each time the lens is removed. The contact lens is to be discarded after the recommended wearing period as prescribed by the Eye Care Professional. When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection system only. |

[a] 3rd party trademarks mentioned herein are trademarks of Novartis AG Corporation.
**Note:** UV = ultraviolet

## Nonclinical Performance Data

The device is made from the same material, and uses the same manufacturing process as the predicate device, VISTAKON® (etafilcon A). Therefore, all nonclinical testing supporting the predicate device in K062614 is also representative of the subject device.

Additionally, in accordance with FDA *Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses,* May 12, 1994, finished product testing for verification of the modified design was conducted to demonstrate that lenses meet specification tolerances.

## Clinical Performance Data

The proposed alternative multifocal design has the same indications, is the same etafilcon A material, and uses the same manufacturing and sterilization processes as the predicate device in K062614. Additionally, the multifocal design type is the same as the predicate device cleared under K073459. Demonstration of the physical and chemical equivalency of the subject device to the predicate devices support the safety and effectiveness of the subject device for an alternate multifocal lens design configuration. Therefore, in accordance with FDA *Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses,* May 12, 1994, clinical performance data to demonstrate substantial equivalence are not required.

## Conclusions Drawn from the Nonclinical and Clinical Tests

Information presented in this Premarket Notification establishes that the ACUVUE® (etafilcon A) Soft (hydrophilic) Contact Lens for Presbyopia, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker for Daily Wear is as safe and effective as the predicate devices when used in accordance with the labeled directions for use.

## Other Information

Not applicable.